EXHIBIT F

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March 21, 2005

Dr. Russell Katz
Director, Neuropharmacological Drug Products
Food and Drug Administration, FDA 120
1451 Rockville Pike, Room 4037
Rockville, MD 20852

Via e-mail and regular mail

Re: NEURONTIN

Dear Dr. Katz:

Enclosed you will find two hundred fifty eight MedWatch forms, most with redacted death certificates. Each represents a suicide of an American who was on Neurontin when he or she took his or her own life. To this day, ***completed suicide*** is not found anywhere on the warning label for Neurontin.

As you know, Neurontin was recommended for approval by the Neuropharmacolgical Drug Products Division of the FDA in 1992. At that time you were Group Leader of the Division and oversaw the FDA's analysis of the clinical data supplied by Parke-Davis Pharmaceuticals, the sponsor seeking approval to sell Neurontin.

Recently, we obtained the FDA's analysis of the New Drug Application filed by Parke-Davis and found shocking information. During your evaluation of serious adverse events that occurred during original clinical trials, the risk of Neurontin causing suicide was both known and a major concern. The FDA clinical reviewer from your Division specifically stated in December, 1992:

> Serious adverse events may limit the drug's widespread usefulness. Depression, while it may not be an infrequent occurrence in the epileptic population, may become worse and require intervention or ***lead to suicide***, as it has resulted in some suicidal attempts during clinical trials. (emphasis added)

In fact, during the clinical trials Parke-Davis reported Neurontin was attributable to four people actually attempting suicide, two more having depression with suicidal ideations and twenty two participants reporting depression so severe it required pharmacologic intervention. Additionally, nineteen of the seventy eight participants who reported depression during the clinical trials had no prior history of depression.

However, since the underlying condition Neurontin helps is such a serious condition – intractable refractory seizures in adults that are not controllable with existing antiseizure medications – your Division recommended approval with "appropriate and prominent labeling for use in a specific population." Clearly, the FDA did not approve this drug with any expectation of use beyond the approved indication. Given the limited population for whom the drug was approved, and the importance of controlling intractable partial seizures, I take no issue with the ultimate approval.

In July, 1996, it came to the attention of the FDA that Parke-Davis was involved in off-label promotions of Neurontin. At that time, Lesley Frank of the FDA wrote to Parke-Davis voicing the FDA's concern:

> Parke-Davis may be promoting Neurontin for 'off-label' uses, i.e., any use beyond the FDA approved indications, in printed promotional materials, in detail or sales presentations to physicians, and through the use of company-solicited physician participation in a series of teleconferences. **These promotions of Neurontin for off-label uses included, but were not limited to, its use in chronic pain, bipolar disorders, and other psychiatric conditions.** As you are aware, Neurontin's only approved indication was for adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. (emphasis added)

Even though the FDA knew Neurontin caused depression that may lead to suicide and that Neurontin's effects were never fully tested on people who suffered from chronic pain, bipolar disorder or other psychiatric conditions, the FDA acted with no urgency. After eleven months, Parke-Davis responded by denying all allegations and the FDA simply accepted their denial. Noteworthy, a former employee of Parke-Davis "blew the whistle" and exposed a plot to defraud physicians and healthcare providers. Through an elaborate scheme of deception, off label sales of Neurontin increased from $23 million in 1993 to $2.7 ***billion*** in 2004. By so doing, they were exposing a vulnerable population of Americans to a drug known for causing depression that leads to suicide, without proper warnings. Ultimately, the Department of Justice in Boston took notice and prosecuted only the illegal marketing and sales practices of Parke-Davis. The prosecution resulted in the company pleading guilty to multiple felonies and paying fines totaling $430 million.

More disturbing, however, is that from 1996 to today, the FDA has taken no affirmative action to require Parke-Davis to advise physicians or their patients of the risks of suicide associated with Neurontin. The FDA never issued a cease and desist letter preventing the off-label sales of Neurontin. The FDA never warned physicians of the known association between Neurontin and suicide. The FDA never required a stronger warning label be affixed on Neurontin prescriptions. The FDA's complete inaction in protecting the health and safety of United States citizens from a known serious risk of an approved drug is highly suspicious given the recent exposed relationships between pharmaceutical companies and the FDA.

On March 31, 2004, you and I had a conference call wherein we discussed the problems with Neurontin's suicidal effects. At that time you were made aware of over one hundred completed suicides and thousands of attempted suicides of Americans while on Neurontin. During that conversation you stated my firm had "the

world's largest data set addressing the question of Neurontin and suicidal behavior that exists" and were most interested in evaluating our findings. Provided I could maintain my clients' confidentiality, I agreed to provide all our raw data at the earliest possible time so as to enable the FDA to act with the swiftness this crisis required. You agreed immediate attention was necessary and advised someone from your office would contact me to coordinate the delivery of the data. Unbelievably, no one from the FDA has called or written me in the past year.

The next month, in April of 2004, my firm's Director of Adverse Event Analysis, Keith Altman, attended a conference on pharmacovigilance sponsored by the Drug Information Association. At that conference Mr. Altman had extensive conversations with Ms. Carol Krueger, a member of the Post Marketing Surveillance Division of the FDA. They specifically discussed the hundreds of known suicides related to Neurontin of which my firm was aware. Ms. Krueger agreed it was important for the FDA to send someone to my office to review the information. Yet again, no one from the FDA has called or written.

Having not heard from the FDA and receiving nearly daily notices of ongoing suicides, my firm pursued the formal administrative process. We filed a Citizens Petition on May 17, 2004, pursuant to 21 CFR 10.35 of the Federal Food, Drug and Cosmetic Act. Our petition sought one simple objective – warn the public of the potential for suicide when taking Neurontin. In our petition we asked the FDA to do two simple things: (i.) require the strongest warning on the label - a black box warning – warning of an association between Neurontin and suicide; and (ii.) require the manufacturer to disseminate "Dear Doctor" and "Dear Healthcare Professional" letters cautioning them to watch for increased depression in patients who were prescribed Neurontin.

Nearly six months later the FDA finally responded to our Citizens Petition. In a letter dated November 5, 2004, we were advised that the "FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the agency." Clearly, if your agency has undertaken any analysis at all, it must have been done so without the benefit of "the world's largest data set addressing the question of Neurontin and suicidal behavior that exists" since no one from the agency has contacted my firm. Nonetheless, we do know FDA officials have had several meetings with the manufacturer regarding the issues of suicide caused by Neurontin. One can only wonder, is it the government's agenda to protect the pharmaceutical company's blockbuster drug at the expense of the safety and security of the American people?

The complete inaction by the FDA to warn an unknowing population that was relying upon the FDA to require warnings for potential adverse events from off-label usage is deplorable. The complicity by the FDA in Parke-Davis's scheme to defraud physicians and consumers is more egregious than the underlying fraud itself. The governmental body charged with the responsibility of protecting the health and safety of Americans has done absolutely nothing to prevent entirely preventable deaths. Such complicity borders on criminality.

Since our conversation of March 31, 2004, my firm has learned of seventy four additional suicides that occurred after that date. Many of these suicides likely could have been prevented had both the treating physician and unsuspecting families been armed with full knowledge of the risks of suicide that was known to both the FDA and the manufacturer.

How many more people have to die before the FDA mandates a black box warning for suicide? How many more people have to die before the FDA mandates a simple "Dear Doctor" letter advising health care providers about a known risk of Neurontin? The administrative process has failed to date. If this failure is in anyway due

to my error kindly advise so I can cure it immediately. If I do not hear from you by April 8, 2005, I will presume your inaction is not based in anyway through a deficiency on my part and I will act accordingly.

I sincerely hope to hear from you.

Very truly yours,

FINKELSTEIN & PARTNERS, LLP

BY: ANDREW G. FINKELSTEIN

AGF/jam
Enclosure

Cc: Dr. Lester Crawford, Acting Commissioner FDA
Dr. Robert Temple, Office of New Product Evaluation, FDA
Hon. Charles Schumer
Hon. Hillary Rodham Clinton
Hon. Maurice D. Hinchey
Hon. Charles Grassley
Hon. John Dingell
Hon. Henry Waxman
Hon. Richard Stearns, USDJ